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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,430	09/22/2003	John F. Shanley	CMI5007USNP1	2375

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Dergosits & Noah LLP
Three Embarcadero Center, Suite 410
San Francisco, CA 94111

EXAMINER	
YABUT, DIANE D	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
11/28/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,430	SHANLEY, JOHN F.	
	Examiner	Art Unit	
	DIANE YABUT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *54-96* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *54-96* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/29/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/29/2010 has been entered. Claims 54-96 are pending in this application.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 03/29/2010 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claims 77 and 94 are objected to because of the following informalities: Both claims recite "through openings" (line 10 in claim 77, line 1 in claim 94), and should rather read --openings--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 54-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreeder et al., hereinafter "**Schreeder**" U.S. Pub. No. **2002/0007209** in view of **Hossainy et al.** (U.S. Patent No. **6,558,733**).

Schreeder discloses delivering an expandable, cylindrical device or stent having a plurality of openings **4** of different shapes and sizes that may be filled with multiple beneficial agents ("therapeutic agent" or "drug") having different concentrations, forms, or eluting profiles, including paclitaxel or rapamycin, or an anti-restenosis drug, as well as a biocompatible coating for delivery to tissue, and a plurality of deformable members **1** forming interconnectable struts and bridging elements (see abstract, Figures 1-2 and 9-13, paragraphs 141-152). However Schreeder discloses that the openings may be filled with polymer/drug coatings with additional barrier coatings or multiple layers of coating with varying drug concentrations (paragraph 152), and therefore a portion of the plurality of openings may be considered to be a first plurality of openings which have a first beneficial agent (a first coating layer) and another portion of the plurality of openings different from the first plurality of openings may be considered as a second plurality of openings which have a second beneficial agent (an additional barrier coating

layer having a same or different concentration of the same drug, the drug being in a different form as being in a different layer).

However, Schreeder does not expressly disclose non-deformable members, or a first plurality of openings containing a first beneficial agent on first and second ends of the device, or a second plurality of openings containing a second beneficial agent positioned on a central portion of the device, wherein the second beneficial agent is different than the first beneficial agent, and wherein the first openings and the second openings are positioned on the non-deformable members. Schreeder also lacks a side hole between the opposite ends having a center axis perpendicular to a longitudinal axis of the device body and configured to accommodate a bifurcation in a lumen.

Hossainy teaches a first plurality of openings **30** containing a first beneficial agent on first and second ends of a stent, a second plurality of openings **30** containing a second beneficial agent positioned on a central portion of the stent, wherein the second beneficial agent is different than the first beneficial agent, and wherein the first openings and the second openings are positioned on non-deformable members **24** or on struts and bridging elements (Figure 4a). See Hossainy, Figure 4a, col. 5, lines 28-30, col. 6, lines 15-25. A side hole may be considered to be the circular section that joins adjacent filaments **22** in Figure 4a, which has a center axis substantially perpendicular to a longitudinal axis of the device body. It would have been obvious to one of ordinary skill in the art at the time of invention to modify Schreeder by having non-deformable members and a side hole, as well as first and second plurality of openings on opposite ends and a central portion of a stent, respectively, with different sizes and beneficial

agents with differing characteristics, as taught by Hossainy, in order to provide a site-specific treatment depending on the intended usage and application of the stent (col. 5, lines 20-34) and in order for the stent to easily expand and contract to thereby facilitate placement of the stent (col. 4, lines 13-15).

Response to Arguments

3. Applicant's arguments filed 03/29/2010 have been fully considered but they are not persuasive.

Applicant argues that neither Scheerder et al. nor Hossainy et al. teach or suggest a device that includes a first plurality of openings containing a first beneficial agent and a second plurality of openings containing a second beneficial agent, wherein the same drug is in both the first and second beneficial agents, but the first and second beneficial agents differ from each other in some way, since Scheerder et al. disclose a device in which all holes have the same composition homogenously or with multiple layers, and applicant has not suggested a reason why Hossainy et al. does not teach the above limitation. The examiner maintains that Scheerder et al. may teach first and second agents having varying concentrations of the same drug based on the particular polymer/drug layer (a portion of the plurality of openings may be considered to be a first plurality of openings which have a first beneficial agent - a first coating layer - and another portion of the plurality of openings different from the first plurality of openings may be considered as a second plurality of openings which have a second beneficial agent - an additional barrier coating layer having a same or different concentration of

the same drug, the drug being in a different form as being in a different layer) and Hossainy et al. teach that opening volumes may vary along the stent (col. 6, lines 15-25) and therefore the first and second agents within first and second openings, respectively, may have varying volumes. Therefore, both Scheerder et al. and Hossainy et al. suggest the same drug is in both the first and second beneficial agents, but the first and second beneficial agents differ from each other in some way (concentration of drug, and volume of drug, respectively).

Conclusion

4. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571)272-6831. The examiner can normally be reached Monday - Friday 9AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Gary Jackson, at (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Diane Yabut
/D. Y./
Examiner, Art Unit 3734
11/17/2011

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 3734